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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,844	12/15/2004	Amnon Sintov	030231-0155	9004
22428 7590 04/29/2009 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			EXAMINER AHMED, HASAN SYED	
			ART UNIT	PAPER NUMBER
			1615	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/517,844

Applicant(s)

SINTOV ET AL.

Examiner

HASAN S. AHMED

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

- Receipt is acknowledged of applicants' amendment, remarks, and RCE which were filed on 24 March 2008 and response to restriction requirement, filed on 25 August 2008.
- Applicants' remarks filed on 24 March 2008 have been considered but are moot in view of the new grounds of rejection.

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 24 March 2008 has been entered.

* * * * *

Election/Restrictions

Applicants' election of Group I in the reply filed on 25 August 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 11 and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

As amended, claim 1 recites the limitation "wherein said microemulsion is a system of water, oil, and amphiphile which is a single optically isotropic and thermodynamically stable liquid solution." After carefully examining the instant disclosure, the examiner respectfully submits that support for this amendment is lacking and the addition of said limitation is new matter. Specifically, the limitation "wherein said microemulsion is a system of water, oil, and amphiphile which is a single optically isotropic and thermodynamically stable liquid solution" is not set forth in the instant specification.

*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, it is unclear whether the limitations “polypeptide” and “protein-based drug” are alternative limitations of the group which includes a local anesthetic, an immunosuppressive, and a neurologically effective drug (*i.e.* one limitation to be selected out of five) or whether one said limitations are to be chosen independently of the group which includes a local anesthetic, an immunosuppressive, and a neurologically effective drug. Clarification is required.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4 and 6-9 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. 2002/0034539 (“Esposito”).

Esposito discloses a transdermal delivery system (*see* [0013]) comprising:

- the transdermal delivery of local anesthetics of instant claim 1 (*see* paragraph 0069);

- the transdermal delivery of neurologically effective drugs of instant claim 1 (*see* [0043], [0046], and [0054]);
- the transdermal delivery of polypeptide (peptide) drugs of instant claim 1 (*see* [0058]);
- the water-miscible tetraglycol of instant claim 1 (*see* [0074]);
- the hydrogel form of instant claim 1 (*see* [0097]);
- the microemulsion of instant claim 1 (*see* [0004], [0013], [0025], [0026], [0079]);
- the ionized polymer of instant claims 2 and 3 (*see* [0070]);
- the guar-based polymer (guar gum) of instant claim 4 (*see* paragraph [0070]);
- the cyclosporine of instant claim 6 (*see* [0045]);
- the hydrogel of instant claim 7 (*see* [0097]);
- the skin penetration enhancer (surfactant) of instant claim 8 (*see* [0077]); and
- the non-ionic surfactant of instant claim 9 (*see* [0077]).

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 2002/0034539 ("Esposito") in view of U.S. Patent No. 5,612,324 ("Guang Lin").

Esposito discloses a transdermal or topical delivery system (*see above*).

Esposito explains that topical drug delivery systems are beneficial because they result in minimal variability of systemic absorption. *See* [0002].

The disclosed delivery system differs from the instant claims in that it does not disclose the hydroxypropyl guar hydroxypropyltrimonium chloride (instant claim 5).

Guang Lin teaches a topical microemulsion system (*see col. 4, lines 29-40*).

The disclosed topical microemulsion may comprise hydroxypropyl guar hydroxypropyltrimonium chloride (*see col. 7, lines 54-55*).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a topical microemulsion drug delivery system using hydroxypropyl guar hydroxypropyltrimonium chloride as taught by Esposito in view of Guang Lin. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a drug delivery system to reduce the variability of systemic absorption, as explained by Esposito (*see above*).

*

2. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 2002/0034539 ("Esposito") in view of in view of U.S. Patent No. 6,417,237 ("Dadey").

Esposito discloses a transdermal or topical delivery system (*see above*).

Esposito explains that topical drug delivery systems are beneficial because they result in minimal variability of systemic absorption. *See* [0002].

The disclosed delivery system differs from the instant claims in that it does not disclose sorbitan monooleate.

Dadey teaches a transdermal microemulsion system (see col. 5, lines 16-18).

The disclosed transdermal microemulsion may comprise sorbitan monooleate (see col. 16, line 23).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a topical microemulsion system using sorbitan monooleate as taught by Esposito in view of Dadey. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a drug delivery system to reduce the variability of systemic absorption, as explained by Esposito (see above).

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 10/343,008 ('008). Although the conflicting claims are not identical, they are not patentably distinct from each other because '008 teaches a transdermal delivery system in hydrogel form using water-miscible tetraglycol and water to dissolve drug (see claim 1).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615